UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA, ex rel. JULIE LONG, Plaintiffs	)	Civil Action No. 16-12182-FDS
vs. JANSSEN BIOTECH, INC., Defendant	)	

BEFORE: CHIEF JUDGE F. DENNIS SAYLOR, IV

MOTION HEARING CONDUCTED BY ZOOM

John Joseph Moakley United States Courthouse
1 Courthouse Way
Boston, MA 02210

April 4, 2022
3:00 p.m.

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PROCEEDINGS

THE CLERK: Court is now in session in the matter of United States vs. Janssen Biotech, Inc., Civil Action Number 16-12182.

Participants are reminded that photographing, recording and rebroadcasting of this hearing is prohibited and may result in sanction.

Would counsel please identify themselves for the record, starting with the plaintiff.

09:31AM MR. LEOPOLD: Good morning, your Honor, Ted Leopold, Casey Preston, Diana Martin, Leslie Kroeger and Poorad Razavi on behalf of the relator.

THE COURT: Good morning.

MR. POSNER: Good morning, your Honor, for the defendant, we have Ethan Posner, Stacey Grisby, Sarah Tremont, Kristen Cobb and Bradley Markano for the defendant.

Good morning. We are in the office, and Ms. Grigsby and I are going to be standing up and sitting

09:31AM down at various places, so hopefully the Court will indulge us as we make the transition to in office arguing.

THE COURT: All right. Good morning.

MR. POSNER: Good morning.

THE COURT: This is a motion hearing on cross appeals from the magistrate judge's discovery decision as

well as I think I also have pending the plaintiff's motion to compel legal opinions.

I think what makes sense from my standpoint is to start with the larger motion, the largest motion, which is Janssen's appeal of the decisions.

Mr. Posner, why don't I give you the floor and you can see proceed as you see fit.

MR. POSNER: Sure. Thank you, your Honor, Ms. Grigsby is going to handle many of those issues. I will handle certain of them. We're happy to proceed issue by issue. If there are issues you would like us to start with, obviously, we can do that.

09:32AM

THE COURT: I'll say don't be afraid to make it simple, or let me rephrase it, to make it clear.

MR. POSNER: Very well, your Honor.

THE COURT: Other than that, I'll let you proceed.

MR. POSNER: Thank you, your Honor.

MS. GRISBY: Your Honor, I'm going to start this schematically. This Court has said that discovery in this case should proceed in phases, and Magistrate Judge Kelley's discovery ruling basically upends your Honor's carefully crafted process.

09:32AM

As this Court described on December 14th, 2020, Phase I discovery was intended to encompass Julie Long's experience, what Julie Long was told, what she read, how

she was trained, how she was supervised, and what happened with the accounts she worked with.

The process was designed to test the accuracy and the viability of Julie Long's claim, and it was focused on Central Pennsylvania, accounts with which Julie Long was involved.

Following this Court's order in phased discovery, both of the parties engaged in negotiations. We negotiated on custodian. Janssen began an extensive review of

09:33AM documents, reviewing over 500,000 documents and ended up producing over 2.8 million pages at a cost of over $1.8 million.

As your Honor is aware, this is in our declaration for Mosquera on ECF Number 252, but starting in August, 2020, relator has moved to expand scope of discovery in Phase I. You'll hear relator repeatedly say that we are no longer in Phase I, that now the focus is in scienter and has pushed this Court to read discovery basically every prior ruling.

09:34AM In response to relator's latest attempt to restart discovery, the magistrate judge did reconsider rulings and has issued rulings that go far beyond the parameters of Phase I, which has proceeded over the last 16 months at a significant cost and burden.

The orders effectively open a new phase of

discovery and require Janssen to search and review from double of the amount of materials in Phase I, it adds 15 new custodians, and it really contravenes this Court's order that this Phase I should proceed and then culminate in summary judgment.

So, specifically, just to lay things out, we are challenging the addition of the 15 custodians, 12 picked by relators, three of them are legal, the additional searches of the yet unidentified employees, who may have had

09:35AM significant involvement in the program, the extension of the discovery cutoff, the response to the relator's untimely RFPs, which were served almost a year after the first two sets of RFPs, the extension of discovery for the relator, and for Karen Trahan, information from accounts from other sources, the government communications, and copies of Janssen's document retention policies that predate when Janssen learned of this litigation, and information about Janssen's privilege log.

These rulings as they are written are sure to

09:35AM spark extensive discovery, in fact, they are sure to spark discovery on discovery, which is what you're seeing, and they're not warranted in this phase of this case, so I'm going to start with the issue about the 12 new custodians.

So, Magistrate Judge Kelley has ordered Janssen to review and produce documents from 12 new custodians, which

would nearly double the volume which Janssen needs to review within this phase of discovery.

Janssen has already provided relator with discovery from 23 highly relevant custodians, so there are six custodians that are most relevant to this phase, and these custodians go up the chain for relator.

There's the relator, there's the regional business managers, who served as relators' direct supervisors during the discovery period, there's the regional business director, which is above that who had national level supervisory authority over the area of business specialists, like Julie Long in the field organization.

09:36AM

Now, seven of these custodians were, in fact, selected by relator, so these were not custodians that Janssen hoisted upon relator, but, in fact, relator, after these negotiations, decided on the seven custodians, many of whom worked at the national level in various functions, including compliance, sales and marketing.

These are all of the vice presidents or above, so these high level positions include vice-presidents and national sales directors. And relator has all the information she needed to select these well custodians at the time. She had access to thousands of pages of discovery. She had access to the discovery produced in the underlying government CID investigation. She is a former

09:37AM

Janssen employee, so certainly to the extent that she is making allegations in this case, she also would have been aware of the people who were in her direct chain of command, so independent of even the prior discovery she received, she herself should have had knowledge of who the custodians would be, and in addition to the seven that the relator had selected, there are also 10 nonoverlapping custodians, whose documents are provided to the Department of Justice.

09:38AM So then, in addition to that, Janssen not only has provided these documents from the custodial searches, but Janssen has also provided documents related to the search of central repositories, as relator would refer to, or noncustodial sources, so those sources include the promotional review committee databases, the ones that are the subject of also another one of relator's motion to compel, and so it is just not the case that relator did not have what she needed when she propounded discovery in the beginning of 2021 in selecting these custodians.

09:39AM So, adding these custodians will not only take a significant amount of time, we said in our declaration, it would take 6 to 9 months, so basically we are starting again. It would add over $1 million or more to this phase of discovery, just this particular order alone, and it's unlikely to add anything meaningful concerning the practice

of support services provided in the account in Central Pennsylvania or concerning relator's specific allegations.

In fact, it's almost unbelievable or not credible that it could add significantly to what relator's specific allegations are given the fact that relator could not identify some of these custodians at the very outset of discovery.

And many of the relator's 28 with the exception of one person, in fact, had no connection to Central Pennsylvania, and that one single custodian was a person who was an area business specialist who began at Janssen in the Central Pennsylvania area after relator left the company in 2016.

So, in terms of the cases that the magistrate judge cited in support of her decision to grant these additional custodians, many of them are in opposite. I think, as we pointed out in our briefing, only one dealt with phase discovery such that it was not, you know, it was not proceeding as this one was, and the other circumstances are different.

Those cases were more complex and involved multiple defendants, so one case involved dozens of defendants, another was multi-district litigation, and the remaining cases where the Court ordered three additional custodians, the Court -- and there's one where the Court

basically skipped a number of custodians.

Again, three additional custodians is far in excess of the 12 custodians that were ordered in this particular matter.

So the next issue we were going to address specifically was the three additional legal custodians. Mr. Posner was going to address that, unless your Honor has questions.

THE COURT: No, go ahead, Mr. Posner.

09:41AM MR. POSNER: So, your Honor, the magistrate ordered us to -- originally the magistrate said you don't have to review the documents from one of the in-house lawyer's files because you're just going to end up creating a massive privilege log, motions for reconsideration. She's now ordered us to review documents from three additional legal custodians.

She didn't identify the legal custodians, so the problem, of course, we're confronted with in this case is that the relator is seeking certainly the longest time

09:42AM period I've ever heard of, which is a 20-year plus time period. They want to now go to 2020, and they've asked for documents from the late '90s and the early 2000's, so now the order appears to require us to go back two decades, figure out all of the in-house lawyers who may have worked on the patient support services, I guess, offer up the

three of them, although it's unclear how that's supposed to work, and then, of course, virtually all those documents are going to be put on a log.

It just seems like an extremely burdensome, you know, waste of time for us to have to research all the lawyers at a large company over two decades, I guess offer up the three legal custodians and then log, I don't know, thousands of additional entries, hundreds, you know, obviously, I don't know what the volume is because I don't know what the custodians are because we haven't looked for it yet, so it just seems really excessive.

09:43AM

We, obviously, have based on the documents we have reviewed created an existing privilege log, we have precisely and carefully logged the privileged material.

Now, that privilege log is going to be exploded and we're going to have to dig around for 20 years to figure out which lawyers worked on this and then log virtually all of their stuff. I don't know what we find.

So, you know, obviously it just seems excessive to us. I think Magistrate Judge Kelley's instinct, initial instinct, on this was the correct one. You know, we had this dispute about whether we had to search the laptop for one of the in-house lawyers whose name is Fred Jimenez.

09:43AM

You know, we know he looked at -- we're not relying on this, I'll get to it this in a minute -- but,

you know, he was a lawyer who served in a capacity where he would review materials, and she originally said you don't have to review his entire laptop because you're going to have to log virtually everything, and after various motions, she's ordered us not to apparently do that but to do additional legal custodians, so we just think it's not, you know, it's too much effort.

Obviously, we all want to focus on getting this case to summary judgment, certainly we want to do that, and
09:44AM that just seems disproportionate to the phasing of this case, so that's our view on the three custodians. I'm happy to take questions, I'm happy to move to the next issue, your Honor.

I guess one of the things I did want to address was expanding discovery to February, 2020. So the magistrate I think initially limited discovery to put the end date at least for Phase I at February of 2016. The relator left in February of 2016.

The case was filed several months later, so,
09:45AM obviously, she has no personal knowledge what occurred after she left. So previously we had a time period of, according to the relator, the late '90s to 2016. Now they want the late '90s through 2020, maybe even through the present. It might be 2023 for a time period if they want something to the present.

Obviously, the materials that post date her departure cannot by definition relate to the claims in the relator's district journal or tenure, which was the point of phased discovery, and the practical, the real world problem, your Honor, in this is we have to redo all the searches, right, we have to go back, to figure out, redo all your searches, put in the last four years of the time period, and now they want us to add a bunch of custodians to that.

09:46AM That alone, according to our estimates, is going to delay things by three to five months, just that alone, so, again, obviously, we're all searching for the right balance for what's proportional.

We contend that it makes sense in Phase I to limit this case at the end of the time period to when she left. Several other courts have done that, have cut off discovery, sometimes liability, but certainly discovery for when the relator leaves the company, so, you know, we just think, I mean, right now we have a 16-career plus time

09:46AM period. We think a 20-year time period is grossly excessive, but, obviously, that's your Honor's determination.

I guess while I'm up here, one other issue, your Honor, was, unless your Honor has questions on the time period issue, they want the communications with DOJ and

OIG HHS since 2016. They want disclosure of information disclosed to DOJ concerning what I will call Investigation Number 2, the investigation from 2016 that resulted in the deprivation by the United States in this case, then they want whether Janssen ever sought an OIG opinion on the programs in question. We told them we did not, and then they want any communications with Medicare that may relate to the claims in this case, although the company doesn't have claims data, the company doesn't submit the claims, the doctors submit the claims. SMS has possession of the claims data.

09:47AM

We've already produced -- let me focus on DOJ for a minute. We've already produced the documents that were produced to DOJ during this investigation. Of course, they span a long time period, although not as nearly as long as the one in this claimed qui-tam, and they cover lots of different custodians. We've produced the cover letters.

We certainly agree to the extent that is in question that what the government knew and when the government knew it is quite relevant to scienter. We will be heard at length on that question shortly.

09:48AM

You know, look, we'd be willing to provide some additional materials provided to DOJ, assuming we get, you know, a contemporaneous production from DOJ and OIG about their investigation.

In any event, on OIG, we told them, we didn't make any OIG advisory opinion requests for the programs in question, we've answered that. On the Medicare, they want communications, I think, between company and Medicare I think relating to the programs in question, which, again, are now spanning 20 years. We told them, well, the government has the claims data. We'd have to search a completely different part of the company to determine whether there were any communications, I guess, with SMS about these programs.

09:49AM

We told them that we don't have anything relating to an OIG advisory opinion request for these programs, and, again, it's about proportionality, right?

The claims data are very important. It's a false claims act case. The government has the claims data. They're supposed to produce that to the parties. They have not, but so we don't think we have to go search some different area of the company to see whether potentially there was some communication with Medicare about the programs in question.

09:49AM

That's where we are on sort of the proportionality as to that issue as well, your Honor. Ms. Grigsby will address the other areas in our appeal. Thank you.

THE COURT: Okay, Ms. Grigsby.

MS. GRISBY: Yes, your Honor. So now I want to

address the addition of further employees, the searches of unidentified employees, and so this is part of the magistrate judge's order on page 15 where there's an order to search and produce documents from current and former employees who had significant involvement in the development, review, approval, monitoring and/or delivery of the support services at issue in this case, whether or not relator happened to name such employees as ESI custodians.

09:50AM Fundamentally, the issue here is that this is not tied at all to proportionality. The parties cooperated and went through an ESI procedure in order to identify the most relevant custodians to relator's allegations and claims, and based on that, Janssen has searched and reviewed those custodians.

What this piece of the discovery order does is basically take -- make unfettered access or an unfettered search for any potential employee who might have had, you know, some kind of involvement in these particular

09:51AM presentations and programs.

So I'll just give you an example just to make this very concrete because there may be further disputes about what is actually significant involvement. It could be that there is a person from accounting who every single time a presentation or a program occurred actually signed the

receipt for payment. That person arguably could have significant involvement in the approval of the support services at issue in this case, but going out and looking for every single individual like that would take hundreds of hours, if not, you know, thousands to review, produce, and make sure that we have gotten every single person who may have touched this program in somewhat of a repetitive way.

Relator's accusation that Janssen somehow is trying to hide the ball or disrupt the process is just false. We have worked with relator throughout a multiple-month negotiation period to review some custodians, including custodians that relator handpicked in order to produce these purpose of documents.

We, according to the ESI protocol, cooperated in identifying the appropriate limits of discovery, and we further agreed that one of the appropriate limits was to limit the number of custodians. This is all contemplated by the ESI protocol itself.

09:52AM

The position that Janssen now needs to just conduct further searches for all employees, for current or former, who had significant involvement, which is incredibly vague, is basically, again, trying to remove any limit that might have previously existed for this discovery process.

And just to bring it back, this is in contravention of the Rule 26 standard, which the touchstone is proportionality. It is not that relator is entitled to every single document that could potentially be, you know, relevant to her claim, including that accountant's, you know, signature on a particular form, it is that, you know, you would look at proportionality to determine whether those documents will be searched.

In our briefing, we talk about the *Sedona* principles, which lay out electronic discovery and ESI protocols, which, again, go to the fact, and they understand that it is neither reasonable, nor feasible for a party to search and produce information from every electronic source that might contain information relevant to every issue in the litigation, nor is a party required to do so.

09:53AM

That is in the *Sedona* principles itself. And the reason is because as we all know with this electronic age, electronic documents proliferate. There could be like we were saying, hundreds of potential people who could have these repetitive documents, but these documents aren't necessarily significant, nor are they necessary to test Ms. Long's claims, and they are not necessarily necessary to say what she knew and to test at summary judgment whether she would have a solid claim.

09:54AM

So we think that the ESI review to date, the review of the dozens of custodians is the appropriate limitation here. We used a well-established manner to review these documents, which is using the ESI protocol in order to respond to the discovery requests, and relator has somehow mentioned that there is some kind of separate process by which we should have been looking for, you know, dozens, hundreds of employee's documents in addition to the ESI protocol. That is inconsistent with ESI discovery itself.

09:55AM

Generally we looked at centralized sources, as I said, but when you decide on the custodians, the reason why is so that the parties do not need to go to every electronic scrap in order to fulfill document requests because, as we all recognize, that comes at substantial burden and substantial expense.

So the order itself just erases that. It really erases any limitations that were in the ESI protocol and basically makes Janssen start over, conduct some kind of broad scour of all of our potential employees during this multi, this over a dozen years in order to find someone who may have had significant involvement and search their documents in addition to, you know, all of the custodians that the magistrate judge previously ordered, so this is really kind of a fishing expedition.

09:56AM

So just kind of on that, I think I've made the point, so I'm going to move onto the third set of our RFPs, and just to make this clear, so relator served 23 requests for production of documents at the very end of Phase I discovery.

That is in addition to two sets of requests for production of documents that the relator had already served. These requests were served nearly 11 months after the Court's deadline for the service of the RFPs, so as our briefing said, our first argument is -- and really these requests themselves are untimely.

This Court on December 18th, 2020 had set a deadline of January 21st, 2021. That's at ECF 89, and this Court set this deadline after the Court made the order that this case would proceed in phases, so it is not the case that the Court was unaware of what the existing structure of this discovery would be in setting the deadline.

Relator has argued that she hasn't had the opportunity to serve these types of discovery requests, and, in particular, she notes that many of her requests go to scienter.

As we've mentioned in our brief, that is just not -- that's incorrect. In fact, the vast majority of issues raised in her prior request for production are ones that she has already accepted the prior requests, and, in

addition, her request, in fact, do touch upon the issue of scienter. That is the existing request that Janssen has already responded to, so, in particular, relator's request for production, which was served on December 30th, 2020 include a request for all management level documents concerning the purpose, reason or objective of providing IOI support, that's RFP 24, and for all management level documents concerning the lawfulness of providing IOI support or any other management advisory services depositions. This is RFP 33.

09:59AM

So it is just not correct to say that relator somehow missed the boat or wasn't provided the opportunity to discover and delve into the issue of what Janssen thought of the lawfulness, nor is it fair to say that relator didn't have the opportunity and didn't, in fact, serve requests related to what Janssen knew.

Relator really can only point to one prior discovery order, and that's the one related to Freddy Jimenez that Mr. Posner just mentioned where she was denied the opportunity to look, to get documents from this particular custodian, and part of the reason was because Magistrate Judge Kelley said that it would just create a very large privilege log.

09:59AM

But other than that, relator has had free reign to look into scienter, and, in fact, has served discovery

addressing that issue. And so we have in our briefing a chart showing just how some of these RFPs match up to some of her prior RFPs. Certainly the wording is different on some of them, but they are the same general, the same general request in many cases.

The magistrate judge reconciled all this by saying if Janssen has already responded to the prior art piece, Janssen can just tell relator that Janssen has already responded, but I guess the question here is if Janssen has already responded, if relator already had opportunity to take discovery on subjects that she wanted, then Janssen should not have to undergo any burden to respond to these untimely requests, requests that were served almost a year after the cutoff established by this Court, and certainly Janssen should not be required to engage in new searches in order to respond to these new RFPs, the dozens of new RFPs that were served.

So if there are no questions on this particular area, then we can move onto the extension of discovery where relator has asked the discovery go back prior to 2006 for relator and for Ms. Trahan, Attorney Trahan, and basically the magistrate before discovery with a couple of exceptions or with a few exceptions, we were looking at 2006 to 2016, when Ms. Long left the employ of Janssen.

Now, the magistrate judge's order basically says

that documents during the development of the program, including defendant's evaluation of the legality of the program, should go back for at least one custodian, Karen Trahan to the start of the program.

So the first point is that these documents or these are not likely to include nonduplicative, relevant materials because we've already produced the information on the programs for over a 10-year period, for a 10-year period, including from the files of the relevant custodians, which include, as I said, the vice-presidents, the national sales directors, people who are quite high up in Janssen.

Relator had no involvement in the origination of the program or any other topic prior to 2006. I mean, that is just undisputed, so it's not clear why we would be going back further than what relator knew or, you know, the origination of the program for which relator was not involved.

But with respect to Ms. Trahan, there just appears to be a misunderstanding about what Ms. Trahan did. Her role as regional business director, it supervises the area of business specialists such activities, and we've produced documents from the time period from October, 2006 through Ms. Long's separation, but basically Ms. Long has said that this means that we should, you know, tie everything to

Ms. Trahan and continue to go back and to look back at anything Ms. Trahan knew.

Relator has already said that it wants to notice Ms. Trahan's deposition, and relator can certainly explore some of these topics at Ms. Trahan's deposition when it takes place and after the parties have some understanding of any further document discovery that is necessary, but at this time to ask Janssen to reach back into Ms. Trahan's documents that now are over 16 years old from now and to basically try to do new searches is overly burdensome.

10:04AM

Basically using the parties' search terms from prior to October, 2006, that would lead to perhaps tens of thousands of documents to review, which at this stage could take one or two months, so this is just not something where we can press a button and do it quickly, and, again, this is kind of outside the phase of the current discovery, which really does relate to Ms. Long and what she knew and what was going on in Central Pennsylvania during the time that Ms. Long was employed at Janssen.

10:04AM

If your Honor doesn't have further questions about this particular area, then I'm going to move onto the information about these when it comes from other sources, so this is the particular part of Magistrate Judge Kelley's order, which is ECF 284 on pages 5 and 6, and the order requires Janssen to produce documents that show or track

certain information from Phase I accounts, but it orders Janssen to search other sources for this information going back to the date when Janssen started to provide IOI to physician practices in Central Pennsylvania.

So we generally don't have reasonably more valuable information to provide on this. We've provided information that is available in what we call the CRM, the customer client relationship management database for the relevant discovery period, so that would cover the Central Pennsylvania accounts as well as the ESI from relator and from her direct chain of command.

10:06AM

In a nutshell, we're just not aware at this point without launching some kind of further investigation that there is any other information, and, again, this part of the order should be overturned in its entirety because the discovery period is really from October, 2006 onward.

Information concerning the specific practices, support services provided by Janssen to physicians' practices outside the statute of limitations period is not at issue in Phase I now, and the burden of identifying what could have been provided going back more than 16 years is incredibly burdensome and certainly disproportionate, the burden is disproportionate in this case.

10:06AM

If your Honor doesn't have any more questions on that, I just want to move to the document retention

policies. So basically there has been an argument by relator that Janssen must produce additional document retention policies, and the magistrate judge's order agreed that document retention policies in place at the time Janssen learned of the litigation are more relevant but required Janssen to produce prior versions of its document retention policies.

So, just to be clear, Janssen has produced its current document retention and preservation policies. That's not disputed. Relator has the particular document retention policies, but what this order does is it not only says that perhaps Janssen should produce the document retention policies from 2017, which is when Janssen learned of this particular investigation and its litigation but instead that Janssen should produce document retention policies perhaps at any point, which would be maybe from 2010 and from 2006, and, again, it's not clear how this is really relevant to Phase I discovery and certainly it's unduly burdensome.

10:07AM

10:08AM

There is no question, Janssen, when it learned of this litigation or this investigation, in fact, was following document retention policies. It's not at all clear what relevance the document retention policy in 2010 would have to any issues this case except to be a fishing expedition.

Relator has not alleged that Janssen failed to properly preserve its documents, and certainly relator has provided no evidence that Janssen has somehow, you know, not followed its standard document retention policies, so, at a minimum, if this Court were inclined to uphold part of the order, Janssen asks that it be limited to the policies that were in effect in 2017, when Janssen learned of the government's civil investigative demand as opposed to some kind of open-ended requirement to produce every single version of Janssen's document retention policies.

10:09AM

So the next issue really is the information about the privilege log. You know, Magistrate Judge Kelley found that Janssen's privilege log met the standards of Federal Law 26, it identifies names of the individuals, whether they were known to the attorneys, information that's required to later evaluate the particular privilege claim.

So, Magistrate Judge Kelley, however, ordered Janssen to provide additional information not required by the protective order, in particular, who the parties are in each communication and what their roles were in the company.

10:10AM

So, again, this is in excess generally of what is required under Rule 26 for a privilege log. Normally you write the -- you indicate who is the attorney and the parties to the communication.

This would be burdensome because we, as attorneys for Janssen, would have to go back and find every single person's name, the nonattorneys, and try to match it with their particular titles and roles during the relevant period for the hundreds of log entries, so that in and of itself would be a bit of a research and a fishing expedition.

It's also, I think we noted in our appeal and the reason below, it's at odds with the particular log format that the relator herself has used. Her privilege log does not contain the names of every single person's title, and it certainly isn't what we agreed to in the protective order and what the parties have agreed to.

So, relator argues that she needs this information to evaluate the privilege claim, but really the only thing that relator needs in order to evaluate a privilege claim is information on whether an attorney was involved.

So, relator has access to millions of nondisclosure documents that relator has access to the organizational charts, to employee rosters, and if relator is interested, to figure out what particular role that person provides, then she is free do so.

I mean, generally this Court recognizes that privilege can extend up and down this organization and that we no longer have use of what they call the control test,

so really in terms of evaluating whether something is privileged, relator does not need Janssen to go through the exercise of writing down titles for hundreds of log entries.

So the next issue really is related to relators' appeal, so I guess does this Court have any further questions on the issues brought up by Janssen's appeal?

THE COURT: No. I'll let Mr. Leopold or the plaintiff suggest their cross-appeal and then let you respond to that.

10:13AM

MS. GRISBY: Yes, your Honor.

THE COURT: Okay. All right. Mr. Leopold.

MR. LEOPOLD: Thank you, your Honor. Mr. Preston is going to respond to the appeal of Magistrate Judge Kelley's order.

THE COURT: Okay. Mr. Preston.

MR. PRESTON: Good morning, your Honor. We just heard pretty much a complete rehash of Janssen's arguments and several briefs that Judge Kelley has closely considered multiple times, and she has rejected these arguments, and the reasons why she's rejected these arguments are set forth in detail in our briefing and in Judge Kelley's orders, but just to summarize your Honor, in December of 2020, your Honor devised a discovery plan in which discovery would evolve.

10:13AM

If your Honor would like, I can go back and I can read the transcript from the December, 2020 scheduling hearing.

THE COURT: Let me get one thing on the table here, okay, we're still in Phase I. I know you keep saying that we're not in Phase I anymore, we're in Phase I, we're still on Central Pennsylvania and policies affecting Central Pennsylvania, okay. We have not evolved, devolved, revolved, we are in Phase I. I have never issued a contrary order.

10:14AM

MR. PRESTON: Your Honor, we don't necessarily disagree with that.

THE COURT: It's my order. Whether you agree or disagree doesn't really matter, the point is that Phase I discovery is the relator's case. We are on the relator's case.

Now, you can define that broadly, narrowly, you know, whatever, whether that means you get names and privilege logs or whatever, fine, but it's the relator's case, not the entire universe, not what was happening in Seattle or Spokane.

10:15AM

MR. PRESTON: Your Honor, none of the discovery disputes before your Honor or before Judge Kelley related to discovery about what was happening in Spokane, this all relates to the services that were provided in Central

Pennsylvania, but, your Honor, when you look at the instructions provided in December of 2020, your Honor did not say that based on the three months of limited discovery that you were providing at that time and based on instructions, it did not say that summary judgment was going to be based on that limited discovery, and your Honor in December or, excuse me, October of 2021, your Honor provided updated instructions in which you clearly said you wanted the relator to provide complete discovery on all elements of her claims except with regard to the field level discovery as to what was happening in other territories such as Spokane, and Chief Magistrate Judge Kelley agrees with our interpretation that the instructions changed in October of 2022.

10:16AM

Her rulings were based on her interpretations of the Court's instructions, and in her orders, she explains how she proceeded and she limited the discovery that we were able to receive particularly on the issues related to scienter, and she didn't provide us full discovery because she was trying to meet the short deadlines that were imposed as part of the earlier instructions.

10:16AM

So, your Honor, the initial instructions, it was supposed to be a very limited period of initial discovery where discovery would help guide what future discovery would take place in the case. This was not to end in a

dispositive motion.

Your Honor, Janssen stretched out that three-month period by objecting to all our discovery requests, refusing to identify key witnesses, and then slowly reviewing and producing documents. So that initial three-month period got stretched out all the way out to November.

Your Honor, in accordance with the Court's instructions during that stretched-out initial period, we focused on the discovery that confirmed that Janssen provided the illegal remuneration at issue in plaintiff's former territory, and that that illegal remuneration was provided under a national directive.

We complied with the Court's instructions to obtain additional foundational information that would enable future discovery in the case to be conducted more efficiently.

Again, in October, your Honor provided updated instructions, again, directing the parties to provide relator complete discovery on all elements of her anti-kickback statute and False Claims Act claims.

Your Honor imposed one restriction, and that's because Janssen provided the same practice management infusion operation support services in all territories. Your Honor wanted discovery of documents and information regarding the delivery of those services and related

interactions with physician practices. This is what we've been calling field level discovery. Your Honor wanted that to be focused on Central Pennsylvania.

Your Honor at that time advised, made it clear that once discovery is completed, it was going to conduct a summary judgment process concerning all elements using the free services provided in Central Pennsylvania as a Bellwether.

After your Honor updated the instructions in October, plaintiff immediately began seeking the remaining discovery she needed to prepare for depositions and to be ready for the Bellwether summary judgment process and trial.

Clear, plaintiff is not seeking --

THE COURT: I never talked about a Bellwether process or trial, and we specifically talked about that Phase I would result in a summary judgment motion. That was entirely -- there's no point in having a Phase I if Phase I is just a label that immediately segues into Phase II, we may as well just call it discovery.

The plan from the beginning was to do discovery on the claims in Central Pennsylvania, again, however defined, and we would talk about that, that would lead to a summary judgment motion, and, of course, you can say, for example, Rule 56(d), you don't have sufficient information to oppose

it, and, you know, that might be fair or not, but that was always the plan.

I'm pretty sure if I go back and look at the record, we can talk about that. This is not an MDL. There's nothing about Bellwether, initial trial, there was nothing about any of that, but continue.

MR. PRESTON: Your Honor, I'm going to read from Judge Kelley's Order 282:

"The Court will not go point by point through its rulings across the multiple hearings. Suffice to say, the Court's aim was to cabin the discovery so the parties could meet the fairly short deadlines set by Chief Judge Saylor, and in this initial stage of discovery, to give relator just enough information to test her claims."

"This Court repeatedly assured relator that however limited discovery was during what the parties came to refer to as Phase I, relator would in the future get more discovery."

"Janssen, which persistently argued that discovery should be as narrow as possible, conceded that Phase I discovery was not the end of discovery. We're trying to look at the claims through a lens, and then you see where you are after Phase I."

"In some instances, the Court persuaded relator to back down from requests by assuring her counsel that she

would be able to take certain discovery later in the case, even when the requested discovery concerned key elements which relator was obligated to prove, such as Janssen's scienter."

"In short, this Court agrees with relator that this Court in an effort to provide her with samples of the evidence limited the number of custodians, limited discovery temporarily and postponed discovery on important issues, such as scienter."

10:21AM "It was understood that the goal of Phase I discovery was to probe the validity of the kickback allegations before considering whether to authorize nationwide discovery. It was not clear what would happen at the end of it."

And that is the guidance that the magistrate judge operated under. Your Honor, so it's not just the plaintiff that was not -- didn't believe that there was a summary judgment at the end of the three-month period of discovery that was initially set, Chief Magistrate Judge Kelley

10:22AM wasn't aware of that either.

Your Honor, after October and we got, received the clarified instructions, we immediately began seeking the remaining discovery needed, mostly focused on scienter but also to expand the number of custodians and other witnesses who possessed relevant documents.

Janssen is asserting that depositions, expert reports, and the Bellwether summary judgment or summary judgment based on Central Pennsylvania, whatever you want to refer to it as, should be based strictly on the small samples of documents that plaintiff received at the initial stage of the discovery period.

Under Janssen's unreasonable interpretation, during the summary judgment process, it's going to require substantial additional discovery. Janssen is free to raise any issue that it chooses during this summary judgment process, so by virtue of the fact that we have only received a sample, any response to the summary judgment is going to require additional discovery.

And then after the summary judgment is complete, discovery would have to reopen again and be completed in order for plaintiff to prepare for the summary judgment she intends to file. This shouldn't be a one-sided process where only Janssen gets to file for summary judgment.

Your Honor, as a result, depositions would need to be opened multiple times, expert reports would need to be supplemented. This approach would significantly delay the resolution of these issues.

Judge Kelley rejected Janssen's version of the plan and determined in light of the updated instructions provided in October, additional requested discovery is

necessary and appropriate under Rule 26's proportionality factors.

This is all basic discovery that's indisputably relevant, such as producing documents from the files of employees who had significant involvement. Nevertheless, Janssen has asserted meritless objections for a second time, some to Judge Kelley's orders requiring it to comply with its basic discovery obligations.

Judge Kelley, who has handled the myriad discovery disputes since the commencement of discovery found that the discovery at issue is relevant and proportional to the needs of the summary judgment process and the case as a whole.

Judge Kelley understands the plan, Judge Kelley understands the case can't move towards resolution while so much relevant information and evidence is being withheld.

Judge Kelley recognizes that it would be a waste of resources and counterproductive to take depositions, have experts prepare reports and conduct a summary judgment review before the completion of document discovery on the central issues in dispute in the case.

Because these are discovery rulings involving issues of mixed law and fact, Judge Kelley's rulings must be afforded significant deference. Judge Kelley did not ignore and misapply Rule 26, nor did Judge Kelley abuse her

discretion or make clear error in assessing the proportionality of the discovery of the needs to the case.

She considered all of the proportionality factors extremely closely, relevant extremely closely, which is evident from her orders. She did not grant plaintiff everything she was requesting. In fact, you denied a significant amount of additional significance discovery plaintiff was requesting.

Janssen can't legitimately complain about any delay associated with completing this discovery, as these delays could have been avoided if Janssen had complied with its obligations concerning this fundamental discovery.

And further delaying the discovery, Janssen is merely rehashing arguments it made earlier to Judge Kelley while improperly trying to assert several new arguments because all of Janssen arguments asserting that Judge Kelley's rulings were clearly erroneous, contrary to law, or meritless, all of its appeals should be denied.

We believe our briefing explains why all the appeals should be denied. I can take the approach of Janssen's counsel and go through each particular appeal and address them individually, your Honor, or if your Honor has specific questions concerning particular appeals, I'm happy to address those.

THE COURT: Why don't you address your cross

motion.

MR. PRESTON: Yes, your Honor. I think Diana Martin is going to address our cross motion.

THE COURT: All right, Ms. Martin.

MS. MARTIN: We filed a limited appeal of a single issue on plaintiff's -- our motion to compel in response to Requests Number 51. In that request, we asked for all documents concerning the review or approval of a contract with a vendor or outside consultant who developed and provided any of the various types of audit support services, including --

10:28AM

COURT REPORTER: Excuse me, you are breaking up.

THE COURT: Same here.

MS. MARTIN: I'm sorry. Is this better? I'm getting some background, too.

THE COURT: Why doesn't everyone but you moot. Let's see if that helps.

MS. MARTIN: Thank you. So this is our limited appeal of compelling a response to request to produce Number 51. That's where we were seeking all documents concerning the review or approval of a contract with a vendor or outside consultant to develop or provide any of the various types of IOI support services provided, including immunology, marketing, commercial agreement routing slips, and we specifically mentioned those routing

10:29AM

slips because we were provided with one single routing slip in the responses to our earlier request for production, and so we included that routing slip as an exhibit to our motion. It's Exhibit A, and we believe that that routing slip shows why these types of documents are relevant here and relevant to proving the key issues of our case.

In this routing slip, it shows that it's -- as Janssen itself says, it's a summary of its agreement with Xcenda regarding the project title is 2013 SOC Site of Care Programs at a projected cost of $600,000, and so this demonstrates that Janssen directed Xcenda to develop and deliver site of care support services to select physician practice groups.

10:30AM

These are services that the plaintiff has claimed in their complaint constitute a legal remuneration and violation of the anti-kickback statute, and this routing slip, so it states that Janssen's, what their objective is in having these services provided, that they're paying these outside consultants a significant amount of money to provide consulting services that value these physician -- that benefit these physician practice groups.

10:30AM

We believe this goes to Janssen acting knowingly or voluntarily in providing these free services. It shows their strategic imperative written right on the document, it's to sustain and grow the infusion model, it shows the

estimated cost of 600,000, which we believe shows this has significant value, it constitutes remuneration.

They deployed the program's according to business need, and they were not offered to all physician practice groups, and this document shows that Janssen's -- it shows who signed off on the project, Janssen's legal department, senior managers, including its vice-president and its president, approved Xcenda in developing and delivering these programs, which we believe all goes to showing that 10:31AM Janssen acted knowingly, voluntarily and willingly in providing these services.

And so the magistrate determined that these documents were not relevant at this stage of discovery, and we believe that decision was an error, that by looking at this single document that we provided, and we believe there must be others out there that also summarize these agreements that Janssen had with these outside consultants that they're relevant and should be produced at this stage before we come to this close of this phase of discovery and 10:32AM enter the summary judgment process.

THE COURT: All right. Ms. Grigsby, are you going to respond to that?

MS. GRISBY: Your Honor, yes, I am responding to that, and also I did want to address a few factual issues that were raised in Mr. Preston's arguments in response to

our appeal, but on these particular routing slips, just to keep it clear and simple, the reason why relator is able to bring this up is because of all the immunology marketing routing slips that are related to the contracts themselves were produced that we found, so relator has the contracts with the service providers, so they already knew the amount because we've already searched for and produced the contracts themselves for the support services.

What relator is pointing to is not just the entirety of its attachments, it's pointing to a single sheet of paper that accompanied the contract and then arguing that Janssen should do some full scale search for these routing slips.

It is duplicative of what relator already has because relator has the routing slips that go with the contracts. Again, it's untimely for the reasons we discussed. This was served in November, 2021, well after the discovery cutoff, and it's cumulative.

Relator has all these pieces of information about the consulting -- about these slips, and they said they believed that there are routing slips out there, but they have no basis to actually claim that.

So, big picture is that this is going to going on these wild goose chases for documents that we have no reason to believe exist could delay this case for a

significant amount of time, and that is in addition to the other things that relator wants.

We are not slow walking it, we are working with all deliberate speed, and our estimate is that this could take up to a year because relator now unsatisfied with what they have want to go and have Janssen look at every single piece of paper or every single electronic file for thousands and thousands of employees over a decade period.

But just to kind of go back and just larger state setting on our appeal, I did hear relator say that we were refusing to identify key witnesses. Again, in the record, there is no basis for that statement. Janssen responded to interrogatories, relator herself has independent knowledge of the people who are in her command chain.

The idea that somehow Janssen waited to provide relator with identification of witnesses such that they could only do it in November, 2021 just is not in the record, and I would actually say that relator should cite to some precise -- a documentation before levying these types of allegations.

The other thing that relator said is that Janssen is slow walking discovery. Your Honor has been closely managing this case along with Magistrate Judge Kelley. Again, there's no indication that Janssen somehow was waiting to provide documents.

As Janssen said, in collecting documents, it performed a review based on these custodial searches and reviewed over half a million documents in order to make production burden relator. In fact, Janssen early on made a production of the government discovery, so that's the discovery related to the government investigation.

And on March 23rd, 2021 before you, your Honor, relator's counsel represented that the documents produced to DOJ would 99 percent provide us the discovery that we generally need. That's in the transcript, page 9, lines 11 through 12, so it is not the case that Janssen has just been sitting and waiting.

We have been responding to relator's requests, we've been adding custodians, we've been reviewing documents in reliance of the fact that relators would comply with what the process was that this Court set out in December of 2020 and not attempt to restart discovery in November, 2021.

And with that and for the reasons we've walked through, these magistrate judge discovery orders would add a significant cost, it would be a significant burden, it would cost, you know, millions of dollars, and it would basically blow up discovery in this case.

We've noted that we believe that they are clearly erroneous and contrary to law, in particular, this Court's

order, Rule 26, as well as the local rules and for all those reasons, we ask that you grant our appeal.

THE COURT: All right. Let's take up the motion to compel legal opinions. Who is going to handle that?

MR. LEOPOLD: I am, your Honor.

THE COURT: Mr. Leopold.

MR. LEOPOLD: Thank you, your Honor. Your Honor, with the understanding and knowledge of where we have come from, the central issue, as your Honor is aware, relators have alleged Janssen knew that the IOI infusion services were unlawful in a way as it relates to the drugs of the Simponi ARIA and the other drug.

10:38AM

Janssen knew that providing the IOI services support would result in false claims to Medicare. Janssen not only in defending against these claims but also asserting affirmative defenses that it cannot be held liable because it believed it was acting lawfully.

Janssen states that the following facts supports their position that it's PRC review and approval of these materials that they undisclose employees, including attorneys reviewed and approved the materials, that undisclosed employees and attorneys reviewed the probable available guidance that these materials would provide, the inaction by the DOJ, and the review of various court rulings.

10:39AM

That being said, Janssen has now asserted into the litigation, it has asserted from day one, not only their affirmative defenses but statements on the record to this Court at a variety of hearings that it has injected as a critical issue that it has acted lawfully.

Janssen, we believe, must produce all of the analysis and reviews that are set forth for not only the PRC but the other various legal counsel inside and outside of Janssen who were involved in these particular reviews of the materials, the IOIs, et cetera.

Your Honor is certainly well versed in these particular issues and understands that these are not only important issues but legally can be very important as it relates to the litigation of these types of claims.

THE COURT: To my understanding, this is a light switch that is either on or it's off, either they are relying on counsel or they're not, there's no middle ground.

MR. LEOPOLD: That's correct, your Honor.

THE COURT: And, you know, if they've made the choice, they're not going to rely on the advice of counsel, they can't hint at it, they've made that decision, and that's that. That's my understanding.

MR. LEOPOLD: That's correct, your Honor. And your Honor raised that issue when your Honor ordered, I

believe it was back in October, if I'm not mistaken, somewhere in October, November to provide the Court with their position. They sort of walked the line at both ends, and they are in lighter form on the record saying that they at this time, I believe it's the words that they used, they're not relying on the advice of counsel.

Your Honor at that hearing then stated, well, don't expect to come back six, eight months from now and change your view, we'll need to address that if and when that occurs. That being said, your Honor, they are talking, respectfully, out of both sides of their mouths.

On the one hand, they're saying they're not relying on advice of counsel, but, on the other hand, they are saying we are relying upon the advice of counsel who reviewed the PRC materials and the lawyers signed off saying that it was lawful, so they are having it, you know, having their cake and eating it, too.

They're saying officially we're not relying upon the advice of counsel, but yet here are the PRC documents, here are the lawyers, here are all the reviews of what we did, and we're relying upon the advice of counsel, so they have thrown in both expressed and implied type of waiver as it relates to these particular issues, and as your Honor has both addressed in court opinions that when you have either the expressed or implied waiver, there are certain

criteria that are necessary to review.

And as your Honor has set forth in both the *United States vs. Gorski* matter as well as the *Diamond Staffing vs. Diamond Staffing*, you applied those particular criteria, and at least the *Diamond Staffing* litigation, you found that there was a waiver.

Again, your Honor, the Catch-22 that we are in is I agree with your Honor, if they are of the position that they are not relying upon the advice of counsel, then they cannot say we are relying upon the PRC and the lawyers involved or any other lawyers within Janssen or outside of Janssen to say what we did or didn't do was lawful.

So perhaps Janssen should state now that they are withdrawing any reliance upon any of the PRC materials, any of the lawyers, and we are standing on our letter that we are not relying upon the advice of counsel, and that will be done with the issue.

But, again, your Honor, I don't want to beat a dead horse, but that is not what they're saying behind the scenes. They are saying to you, your Honor, we are not relying upon the advice of counsel, but in all of the discovery responses and all of their affirmative defenses and all the statements to the magistrate and all of the statements to your Honor in the past hearings, they are saying that we are relying upon the advice of counsel as it

relates to all of the approvals that were done related to the PRC and in other aspects of in-house counsel and outside counsel.

So really the burden is on I would say Janssen at this point in time to say with specificity that they are withdrawing any reliance upon the PRC, any reliance upon the lawyers, and we are not relying upon the advice of counsel.

If they are not able to say that, then they have waived that issue, and we should be entitled to receive all of the materials that address that issue.

10:44AM

THE COURT: All right. Mr. Posner.

MR. POSNER: Your Honor, let me begin what is undisputed in this case, all right. 1, we have carefully withheld the documents that were privileged, logged them on the privilege log.

We have not revealed any substantive legal advice at any time at all. Mr. Leopold is simply wrong. The reason he didn't cite or quote from any document in that recitation is because if you look at the facts, if you look at the documents, we have not in any way placed legal advice at issue in any materials at all. We have carefully logged the privileged documents, we have declined to invoke the advice of counsel defense which, by the way, is very narrow. Your Honor set out a very demanding five-part test

10:44AM

in the *Gorski* case about what that is, and we have been very careful, there has been no waiver of privilege in this case at all.

The First Circuit has made it very clear in *Keeper of Records* case that an implied waiver is very rare. The client has to explicitly reveal an attorney communication and rely on that communication or assert reliance on attorney advice as a defense. None of that has happened here. You will not find any example of that in any exhibit attached to the relator's motion at all.

10:45AM

Now, we haven't placed any -- we haven't revealed any attorney advice, we haven't cited to any legal advice, the substance of any advice, much less that we're going to rely upon.

We disclaim that we are going to rely on the advice of counsel defense. Our interrogatory responses, all it says is that one lawyer reviewed, you know, had the job title of reviewing programs like this.

The law is completely settled, including your

10:46AM

Honor's decision in *Gorski* that nearly revealing the fact that a lawyer reviewed something without revealing the substance of that communication is not a waiver. If the contrary were true, that would be a dramatic change in the law.

Now, all we have said, look, the cases here, your

Honor, overwhelmingly support it. Let's look at your Honor's decision in the *Diamond Staffing* case. It's a long time ago, it's 2005. The party there offered an affidavit of the lawyer and the lawyer's advice to be rebut an allegation of bad faith. We have done none of that. The party disclosed the lawyer's work, it was a trademark case, and the defendant said, well, we have a lawyer check the trademark and take all these steps, and so the lawyer is really relevant.

10:47AM The way I read the Diamond Staffing, your Honor still didn't find a waiver and allowed the party to decide about the advice of counsel.

The touchstone of all of these cases, of Gorski, of Diamond Staffing, of the *In Re: Keeper of the Records* in the First Circuit, you have to exquisitely place the lawyer's advice, and you have to say what the advice is and that you're relying on it. You have to meet all these factors that your Honor set out in the *Gorski* case.

And in the *Gorski* case, you know, your Honor read 10:47AM a lot of opinions, that was a motion to disqualify the Mintz firm, really focused on that, and there the defendant was going to argue that Mintz was involved in the events in question and the conduct was lawful because they hired Mintz, and the Court still said, well, as long as you're declining to invoke the advice of counsel defense, you

know, that's sufficient for now. We've been very clear, we are not waiving, we are not invoking the advice of counsel defense.

Now, let me get to the promotional review committee materials. That is a very -- all major pharmaceutical companies have this process. Sometimes they call it, you know, the review committee or promotional review committee. It's a multi-disciplinary committee that produced thousands of pages of documents relating to the PRC with one very significant exception, we have not produced any criminal shot use (ph) from the PRC process, but, you know, it involves medical, legal, you know, sales, marketing, you know, advertising, and they review materials before first use, including the materials that are now alleged to be kickbacks. Obviously, the idea that Janssen knew these were unlawful is ridiculous, not before your Honor. Obviously, we deny that.

10:48AM

It's very common. We have never argued that the PRC is tantamount to a legal review, we're not arguing that the PRC process, you know, per se makes it lawful. We withheld any privileged material from the PRC process itself. Your Honor, the PRC is one of the ways in which Janssen and more candidly many other pharmaceutical companies comply with the law. It's part of their compliance process.

10:49AM

The idea that the PRC or some other aspect of the company's compliance program waives the clerical issue would be a dramatic escalation and a dramatic departure from settled law in this district and in this circuit.

There are plenty of cases that allow a defendant to say we operated in good faith for many reasons. One of the ways is, well, we have compliance policies. Guess what, we've produced these detailed compliance policies to the relator. They have hundreds of pages of our compliance policies, which actually go to some of the very practices in this case. None of that waives the privilege, none of that.

10:50AM

The PRC process is another way in which companies comply, and there are many cases that allow a company to rebut an allegation of bad faith or to disprove science by allowing reliance on a compliance policy, and the idea that that would constitute a privilege waiver would be a massive development for corporate clients in this district.

We all know how active the U.S. Attorney's Office has been in this district in healthcare cases. And, in fact, the justice department, I think the Associate Attorney General just gave a speech. You know, the Department of Justice often gives speeches that say, you know, we encourage companies to have compliance programs, and we'll factor that into our analysis, but the

10:50AM

United States went further.

The United States said that a compliance policy can actually rebut scienter. It would come as quite a surprise to the United States, certainly corporate defendants in this district if that came with some sort of implied privilege waiver because the implication of barring the reliance on the PRC process as, one, we're not talking about the legal advice.

We've redacted that, we've excluded that, we're not relying on explicit legal advice that came out of that PRC process, but the fact that they have a multi-disciplinary process that imputes a lawyer that we can rely on without waiving. The law is clear. Your Honor cited to it in *Gorski*.

The mere fact that a lawyer reviewed something is not privileged. And, in fact, if you look at Exhibit, I think it's Exhibit F and G, the copy review approval form, all that it was disclosed is, well, the lawyer looked at it on this day, and that's the lawyer's signature, but there's no responsive, it doesn't say approved or lawful or, you know, if there were any substantive communications, that's exactly the kind of thing that we withheld.

And the mere fact that a lawyer reviews or signs something like this -- I mean, if this had otherwise been privileged, the relator would certainly say we would have

to log the fact that the lawyer reviewed it, and the law is clear, you said it in *Gorski*, you know, you cited a D.C. Circuit case in *White*, the mere fact that a lawyer reviewed something doesn't constitute any kind of waiver, you know, companies can rely on that. That's been clear for years. We're not relying on the legal advice, we're not saying that the lawyer reviewed it and it's lawful. That's the kind of affirmative invocation, you know, that sometimes can get at the advice of counsel. We've been very clear to stay far away from that.

10:52AM

This is a very important issue to us, your Honor, and, obviously, if your Honor, you know, has concerns about what are one of our positions might be, it would be better to know that now, you know, I hope summary judgment is in a few months and not in 18 months, but, you know, if your Honor has concerns or questions about the idea that I'm saying here and the conduct is lawful, and that's some sort of waiver, what am I supposed to say? Of course, I think the conduct is lawful. That's not an implied waiver. Obviously, there are no cases that support that proposition.

10:53AM

All we said in our letter, we were required to state in December of 2021 whether we were going to vote. We were clear that we were not going to, and all we said was, and, we, of course, we didn't have any motion on this,

Mr. Leopold is making points about a motion based on discovery that hasn't happened in a motion we haven't filed yet. That may be not yet filed depending on how your Honor rules on the reconsideration issues, that may not get filed for awhile, but all we've said is, you know, we've reserved our rights, and on all other available arguments and defenses, including the Janssen, followed a business practice of having a multi-disciplinary committee that included a lawyer review and approve the challenged presentations and resources.

10:54AM

We're going to reveal the lawyer's advice, we're not going to say the lawyer said it was Weikel, and, of course, we cite a case in the letter which says exactly that. We cited a case in the Northern District of Georgia that you don't waive the attorney-client by presenting evidence regarding how they manage and structure their business, and that includes that you consult with counsel.

And, you know, we cited the *White*, the D.C. case that your Honor cited in *Gorski* about a general assertion lacking substantive content. That's what it lacks. We're not providing any substantive content, all we're saying is we have a PRC process composed of 7 or 8 groups, including a lawyer, that's all we're saying, not revealing any of that advice.

10:54AM

MR. LEOPOLD: Your Honor, may I briefly respond?

THE COURT: Briefly.

MR. POSNER: Does your Honor have questions or concerns about anything?

THE COURT: Let me hear from Mr. Leopold.

MR. POSNER: Sure.

MR. LEOPOLD: Just briefly, your Honor. Thank you. Janssen has been on the record at almost every hearing with the magistrate and several hearings with your Honor that they are relying on the PRC and the lawyer on the PRC.

10:55AM

One of the things that Janssen did not respond to is if we look, for example, not at Exhibit G but if we look at Exhibit D that sets out the review and approval process for the PRC for the legal attorney on that committee, the responsibilities are as follows and I am quoting:

It assures that the PRC review materials comply with applicable state and federal laws and corporate policy, including but not limited to those relating to FDA advertising or promotion, Medicare and Medicaid requirements, healthcare compliance, False Claims Act, Layman Act, fraud and liability abuse laws, and product liability, then if you go to Exhibit G, it specifically has the lawyer's name on there who did that review of that particular review.

10:56AM

Now, Janssen is of the view that, oh, no, we're

not relying, we have expressly stated to the Court that we are not relying on advice of counsel, but, by inference, the fact that a lawyer sat on a PRC committee to review this is sufficient.

Now, how we would be able to rebut the inference to a jury or to the Court that everything is kosher because the lawyer sat on that committee if we're not having the ability to depose either the lawyer, look at the documents, the supporting documentation, the opinions of the lawyer? I mean, it's a double-edge sword, again, it's a shield and a sword.

10:57AM

10:57AM

And I would address the issue of the *Gorski* case because I do think that it's insightful for us on the implied waiver because your Honor has written, there's three criterias. One is the party takes some affirmative steps, such as filing a pleading here, several affirmative defenses stating that they did not do anything wrong, they didn't knowingly falsify or violate any laws, then the second criteria is whether the affirmative act put the privileged information at issue.

Clearly, the PRC and other documentations along these lines put it at issue and whether upholding the privileges would deny opposing party access to the information vital to the case.

Clearly, again, when you have a PRC and

specifically the legal counsel in there is reviewing as his or her responsibilities all of the issues that are set forth that makes the quantifying decision as to whether or not this is legal or not puts that at issue, and we have the -- I believe we have the right to rebut those issues by taking discovery and looking at the documents that the lawyers themselves used to say and check off that it is all legal.

So, your Honor, again, they can't have it both ways. It's either all off the table or it's all on the table, but by merely writing a letter we're not relying upon the advice of counsel but we are relying upon lawyers sitting on the PRC as that being sufficient without us being able to appropriately investigate, cross-examine and do due diligence, I think is extremely prejudicial to the plaintiff.

10:58AM

THE COURT: All right. Just one question, Mr. Posner. How -- what's your response to that? I mean, I'll paraphrase the argument, if you say we ran this by a PRC and the PRC had a lawyer on it, isn't that implicitly arguing that the lawyer approved it?

10:59AM

MR. POSNER: Well, no, because, I mean, you can't reconcile that with the cases that allow -- I mean, the *Bacchi* case, you know, there's a line of cases that obviously says the mere -- you can cite that a lawyer

reviewed something, but what you can't do is provide the substantive legal advice behind that, so all we have -- look, we haven't made any argument, but all we said in our letter of December of 2021 was that we reserved the right to argue that Janssen followed a business practice of having a multi-disciplinary committee that included a lawyer review and approve the challenged presentations.

I don't exactly know how we are going to argue this. I don't even know when summary judgment is going to be. We're look at a lot more discovery.

11:00AM

What we were following was the line of cases that said that you can cite to the fact that a lawyer reviewed it, what you can't do is provide the substantive legal advice, which we're not going to do and we haven't done, and, you know, it's an argument that hasn't been made yet, but I don't think we have a plan to say, well, it's lawful because a lawyer reviewed it. We've never said that, never, not once, in any of these papers have we said that.

The PRC is part of the way that the company has, you know, complies with the law, and they have compliance policies, we're going to rely on those.

11:00AM

Now, we may not rely on them to say, well, it's per se lawful because we have these compliance policies. No, it's a factor in the scienter analysis. You know, if you look at the -- I mean, if you look at the, you know,

one of Magistrate Cabell's case, the *Bacchi* case, the *Bacchi* case rejects specifically the idea that invocation of defenses, like "reasonable interpretation" or "in a court with industry practice" specifically rejects the idea that that's an implicit waiver.

The party, Magistrate Cabell said in the *Bacchi* case, the ACCA Tribe, has to explicitly the legal advice at issue and claim reliance on specific legal advice that the conduct was lawful, we have not done that, and we don't have plans to do that, but, you know, there's a line of these cases that say as long as you're not revealing the substance of the communication, you can cite that a lawyer reviewed something.

11:01AM

It's certainly our plan to rely on a multi-disciplinary review process in the PRC. You know, what exactly -- you know, look, by the way, Mr. Leopold cited the policies. The policies talk about the lawyer's role, but we have no plans to argue that that makes it per se lawful. All we've done is produced a policy. We haven't made any argument about the policy.

11:02AM

I mean, if I withheld the policy because it was privileged, we'd have a motion to compel on our hands. This is a broadly-issued policy, so we produced it. It describes the roles of the members, but we're not going to be -- we don't have to plans to argue, well, see the lawyer

had a rollover during the legality and therefore the lawyer reviewed it, so, therefore, it's per se legal.

There are many ways that you can make arguments that are short of that. We haven't made any of these arguments, and, obviously, our view is it's completely premature and won't opine on a motion we haven't filed based on facts that haven't even been developed yet in discovery.

But the answer to your question, your Honor, to be simple and clear about it is that the law is clear that a company can cite a lawyer's review as long as they don't provide the underlying substance of the advice. That's what the cases seem to say, your Honor.

11:03AM

THE COURT: Okay. I'm going to -- we've been at this for an hour and a half, I'm going to shut this down, and I'm going to take the three motions under advisement.

MR. POSNER: Thank you for your time, your Honor.

THE COURT: Thank you.

(Whereupon, the hearing was adjourned at 11:03 p.m.)

C E R T I F I C A T E

UNITED STATES DISTRICT COURT)
DISTRICT OF MASSACHUSETTS) ss.
CITY OF BOSTON)

I do hereby certify that the foregoing transcript, Pages 1 through 63 inclusive, was recorded by me stenographically at the time and place aforesaid in Civil Action No. 16-12182-FDS, THE UNITED STATES OF AMERICA ex rel. JULIE LONG vs. JANSSEN BIOTECH, INC., and thereafter by me reduced to typewriting and is a true and accurate record of the proceedings.

Dated April 7, 2022.

s/s Valerie A. O'Hara
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VALERIE A. O'HARA
OFFICIAL COURT REPORTER